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TITLE: Effectiveness of Acupressure Treatment in Pain Management and Fatigue Relief for Gulf War Veterans

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RECIPIENT: Cleveland Clinic, Cleveland,
Ohio
Cleveland, OH 44195

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14. ABSTRACT This study will provide symptomatic veterans with acupressure treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupressure group (to receive acupressure treatment) and control group (Reiki). The acupressure treatment will be offered twice per week for 6 weeks. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupressure group vs control group) and between different stages (before treatment vs. after treatment) within the same group.				
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I. INTRODUCTION

This study will provide symptomatic veterans with acupressure treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupressure group (to receive acupressure treatment) and control group (without acupressure treatment). The acupressure treatment, twice per week for 6 weeks, will be offered by licensed acupressure practitioner, with at least 5 years of clinical experience, who have received 20 hours of training related to symptoms of GWI. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupressure group vs. control group) and between different stages (before treatment vs. after treatment) within the same group.

Aim 1 is to investigate the effectiveness of acupressure for fatigue relief and pain management in veterans with GWI.

Aim 2 is to investigate the relationship between EEG measures, specifically the corticomuscular coherence and power spectra in theta band, and the clinical measures.

II. KEYWORDS

Acupressure, Reiki, Gulf War Illness, fatigue, chronic headache, musculoskeletal pain, electroencephalography, non-invasive, pain management, quality of life

III. STUDY PROGRESS

The study received continuing renewal approval from Cleveland Clinic IRB with expiration date of 10/18/2016. No cost extension of a 12-months of period has already been approved. The study is being conducted at only one site – Cleveland Clinic Foundation.

Dr. Vernon Lin (co-PI in the original proposal) replaced Dr. Yin Fang as the study PI (with DOD approval). The changes in study personnel delayed study start-up and progress. To address the change in the investigative team, Dr. Lin brought in experienced clinicians and researchers to deliver the study interventions and assist with subject enrollment and study coordination. Vinoth Ranganathan is no longer with Cleveland Clinic, but is available on a limited basis (no cost) to assist the study team with technical issues.

Investigational Site	Investigators
Cleveland Clinic Foundation 9500 Euclid Avenue, Cleveland, OH 44195	Vernon Lin MD PhD John Lee MD Juliet Hou MD Xiaofeng Wang PhD Guang Yue PhD Honglian Huang MD PhD Jamie Starkey LAc Xiaoming Zhang PhD Shuyun Jiang MD (Consultant) Ernie Betz (Consultant – Reiki) Wenning Zhao (Consultant) Yin Fang PhD (Consultant) Vlodek Siemionow PhD (Consultant)

Dr. Bayram, a rehabilitation/neuroscience researcher from Kessler Rehab has agreed to be a technical consultant and will assist the research team with initial equipment setup and data analysis. As a result of Dr. Bayram's addition, the research team has purchased a new 8-channel EEG/EMG system that is more suitable for study purposes. This system has not only reduced subject preparation time, but also streamlined data collection and improved data quality. Research subjects have welcomed the significant decrease in set-up time and post-recording clean-up time. We currently use a digital hand grip system made by AD Instruments (manufacturer of the EEG/EMG system we currently use). This allows us to reliably and continuously collect hand grip data. Subjects have responded positively to the new data collection system.

Study Advertisements

The online ads has been approved by IRB and placed on contextually relevant sites with content related to Gulf War Veterans/syndrome/illness. Google generates keyword recommendations on what content is most likely relevant to the target, and the ads have been placed within those sites. CCF marketing and study team monitor them for engagement. In order to accelerate recruitment, we also submitted amendment to local IRB to mail the advertisement letters to Gulf War Veterans. The list was purchased by Cleveland Clinic Marketing Services specifically to be used for this research study. The study team will continue to work with the staffs at Cleveland Clinic to screen and enroll subjects.

Number of Subjects

Seven subjects (four in the Acupressure group and three in the Reiki group) have been recruited for the study. Of these seven subjects, two have completed the study, one withdrew from the study due to personal reason, and the other four are in various stages of the study.

Study findings

Two subjects have completed the study protocol (one subject for Acupressure and one for Reiki). Subjects received Acupressure or Reiki treatments 40 min/day, 2 days/week for 6 weeks. Clinical measurements include the following: pain measurement of Brief Pain Inventory (BPI), fatigability measurement of revised Piper Fatigue Scale (rPFS), and SF-36.

For the Acupressure group, a six-week Acupressure protocol was performed. Clinical measurements (BPI and rPFS) were evaluated before, during, and after the protocol. The baseline scores for the BPI and rPFS were 4.1 and 5.7, respectively. After 6 weeks of the acupressure treatment, the scores decreased to 3.5 for BPI and 4.5 for rPFS, respectively. When the treatment was discontinued for four weeks, these scores had the following increments (BPI, 5.2; rPFS, 6.0).

For the Reiki group, a six-week Reiki protocol was performed. Clinical measurements (BPI and rPFS) were evaluated before, during, and after the protocol. The baseline scores for the BPI and rPFS were 5.9 and 5.5, respectively. After 6 weeks of the Reiki treatment, the scores were 2.8 for BPI and 4.5 for rPFS, respectively. When the treatment was discontinued for four weeks, these scores had the following increments (BPI, 5.6; rPFS, 6.5).

A 6-week Acupressure intervention produced fatigue relief and pain alleviation similar to Reiki in veterans with GWI, indicating that acupressure may be a potential noninvasive therapeutic technology for fatigue relief and pain management in veterans with GWI.

Summary of Anticipated and Unanticipated Adverse Effects

N/A

Problem Areas

The initial proposal included Cleveland VA as a recruitment site. However, in accordance with Cleveland VA recommendation, the study will recruit subjects only at Cleveland Clinic. Study subjects will have to visit Cleveland Clinic two times per week for the intervention. This will significantly limit the number of subjects willing and able to participate in the study. Limited access to Veterans outside Cleveland VA has significantly slowed subject enrollment. Now the study team is advertising the study through Veterans support organizations, ClinicalTrials.Gov. The study team will continue to work closely with the staff at Cleveland Clinic to recruit more subjects in the following 8-10 months.

IV. KEY RESEARCH ACCOMPLISHMENTS

N/A

V. CONCLUSION

The results from the two subjects who have completed the intervention look promising and are indicative of the Acupressure potential for pain management and fatigue relief in veterans with GWI. Pain scale and fatigue scale decreased during the intervention. Continuation of the study will allow us to better understand the efficacy of acupressure for fatigue relief and pain management in veterans with GWI. The study staffs have gained valuable knowledge related to acupressure and its potential for fatigue relief and pain management in veterans with GWI. This knowledge may lead to further refinement of the protocol as well as advancements in acupressure intervention for veterans with GWI.

VI. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

N/A

VII. INVENTIONS, PATENTS AND LICENSES

N/A

VIII. REPORTABLE OUTCOMES

Seven subjects (four in the Acupressure group and three in the Reiki group) have been recruited for the study. Of these seven subjects, two have completed the study, one withdrew from the study due to personal reason, and the other four are in various stages of the study. The results from the two subjects who have completed the intervention look promising and are indicative of the Acupressure potential for pain management and fatigue relief in veterans with GWI. Continuation of the study will allow us to better understand the efficacy of acupressure for fatigue relief and pain management in veterans with GWI.

IX. OTHER ACHIEVEMENTS

N/A